

830010-2002.2

09/975,812

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Pasternak et al.
Serial No. : 09/975,812
For : TOPICAL ANESTHETIC/OPIOID
FORMULATIONS AND USES THEREOF
Filed : October 11, 2001
Examiner : Ted Criares
Art Unit : 1617

745 Fifth Avenue
New York, NY 10151

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I hereby certify that this paper is being facsimile transmitted to the
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Signature

February 18, 2004

Date of Signature

SECOND SUPPLEMENTAL RESPONSE TO OFFICE ACTION

Mail Stop Non Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is filed in further response to the February 26, 2003 non-final Office Action.
The Commissioner is hereby authorized to charge any additional fee which may be required, or
credit any overpayment to Account No. 50-0320. Kindly amend the application, without
prejudice, without admission, without surrender of subject matter, and without any intention of
creating any estoppel as to equivalents, as follows.

830010-2002.2
09/975,812AMENDMENT

Kindly amend the application, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

In the Specification

Page 26, line 11, please amend the paragraph thereat as follows:

The fixed ratios of lidocaine/morphine (0.5), lidocaine/buprenorphine (0.4) (2.4) and lidocaine/levorphanol (0.5) were used.

Page 28, please amend the table thereat as follows:

Table 2

Effects of fixed doses of morphine or lidocaine on the analgesic potency of various agents.

	ED ₅₀ (mM)	95% Confidence limits	Shift
Lidocaine alone	1.52 5	(2.0, 3.4)	
+ morphine 1.5 mM	1.0	(0.4, 1.8)	2.5
+ morphine 3.0 mM	0.8	(0.6, 1.1)	3.1
+ morphine 4.5 mM	0.7	(0.5, 0.9)	3.6
Morphine alone	6.1	(4.3, 8.4)	
+ lidocaine 0.45 mM	3.6	(2.6, 4.5)	1.7
+ lidocaine 0.9 mM	1.5	(0.9, 2.6)	4.1
+ lidocaine 1.8 mM	1.3	(0.6, 1.3)	4.7